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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,054	07/15/2003	Jan K. Caers	17595 (BOT)	8812

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EXAMINER

ANDERSON, CATHARINE L

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/621,054	Applicant(s) CAERS ET AL.	
	Examiner C. Lynne Anderson	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-9, 12-15 and 17-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-9, 12-15 and 17-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/22/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 7 June 2006 have been fully considered but they are not persuasive.

In response to the applicant's argument that Gardiner fails to disclose first and second plurality of perforations that are non-overlapping, it is noted that Gardiner shows first and second plurality of perforations in figure 5. The first plurality comprising the four perforations labeled Mon, Tue, Wed, and Thurs, and the second plurality comprising the three perforations labeled Fri, Sat, and Sun.

In response to the applicant's argument that Whitmore also fails to disclose first and second plurality of perforations, it is noted that the first and second plurality disclosed by Whitmore comprise rows and columns, respectively. The first and second plurality may be defined as a portion of one row and a portion of a column such that the first and second plurality do not overlap. Therefore, Whitmore fulfills the limitations of the claim.

In response to applicant's argument that the combination of Walker and Gardiner is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the teaching of Gardiner of the use of a device having a plurality of perforations during injection is applicable to the method disclosed by Walker

because the general method of injecting is common to the injection of both insulin and botulinum toxin. Therefore, the teaching of Gardiner is applicable to the method of Walker.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Gardiner (4,228,796).

Gardiner discloses a device 10, as shown in figure 1, comprising a material 12 with an upper face, a lower face, and a plurality of perforations extending completely through the material. The plurality of perforations are comprised in non-overlapping first and second plurality of perforations, as shown in figure 5, the first plurality comprising the four perforations labeled Mon, Tue, Wed, and Thurs, and the second plurality comprising the three perforations labeled Fri, Sat, and Sun. The device is for assisting in making injections, and therefore is fully capable of being used to assist hyperhydrosis therapy.

With respect to claims 2 and 8, the material 12 has an exterior border that is not perforated, as shown in figure 5.

With respect to claims 3 and 9, the material 12 is flexible to that the exterior border is in contact with a dermal area during use, as shown in figure 5.

Claims 1-2, 6-8, 12-13, and 22-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Whitmore, III et al. (6,036,632).

Whitmore discloses a device 10, as shown in figure 1, comprising a material 14 with an upper face, a lower face, and a plurality of perforations 12 extending completely through the material. A first group of perforations, the columns, are spaced apart by a first uniform distance. A second group of perforations, the rows, are spaced apart by a second uniform distance that is not equal to the first. The first and second plurality may be defined as a portion of one row and a portion of a column such that the first and second plurality do not overlap. The device is for assisting in making injections, and therefore is fully capable of being used to assist hyperhydrosis therapy.

With respect to claims 2 and 8, the material 14 has an exterior border that is not perforated, as shown in figure 1.

With respect to claims 6-7 and 12-13, the perforations have a first end opening at the upper face and a second end opening at the lower face, wherein the diameter of the first opening is greater than the diameter of the second end, as shown in figure 4.

With respect to claims 22-24, the distance between the perforations is 0.5 cm, as disclosed in column 1, line 47.

With respect to claims 25-26, the perforations have a conical shape, as shown in figure 5, and therefore the cross section of the perforations can be drawn as two non-parallel lines.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-15 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker (US 2002/0086036) in view of Gardiner (4,228,796).

Walker discloses all aspects of the claimed invention with the exception of the use of a device having a plurality of perforations. Walker discloses in paragraphs [0087]-[0088] a method for assisting in hyperhydrosis therapy comprising determining a dermal area of a patient which exhibits hyperhydrosis by use of an iodine starch test, marking the area to be treated, and injecting botulinum toxin at the location of the mark.

Gardiner teaches the use of a device comprising a material having an upper face, a lower face, and a plurality of perforations to assist in marking a dermal area to be given multiple injections, as disclosed in column 40-43. The device allows the user to mark areas that need to be injected and identify areas that have already been injected, as disclosed in column 1, lines 29-39.

It would therefore be obvious to one of ordinary skill in the art at the time of invention to employ the device of Gardiner in the method for assisting hyperhydrosis therapy of Walker to allow for the marking of areas that need to be injected and identification of areas that have already been injected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Lynne Anderson whose telephone number is (571) 272-4932. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CMA
cla

August 20, 2006

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

